

IX. Summary of Safety and Effectiveness

SUBMITTER: United States Surgical
A division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Luis Nesprido

DATE PREPARED: July 10, 2001

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis
Spinal Interlaminar Fixation Orthosis
Spondylolisthesis Spinal Fixation Device System

COMMON NAME: Stainless Steel Spinal Rod System

PROPRIETARY NAME: Spiral Radius 90-D™ SST System

PREDICATE DEVICES: USS's Spiral Radius 90-D™ System – K992784 &
K000009 & the Rogozinski Spinal Rodding System –
K954696

INTENDED USE: The components of the Spiral Radius 90-D™ SST System are indicated for spinal fixation.

When used as an anterolateral/anterior system consisting of rods and screws, the levels of attachment are the lumbar, thoracic and cervical spine. The points of attachment and methods are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T6-L5) and the anterior vertebral bodies of the cervical spine. The Indications are degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or failed previous fusion (pseudoarthrosis).

When used as a nonpedicle posterior system consisting of hooks, crosslinks and sacral/iliac screws the levels of attachments are the lumbar, thoracic and cervical spine and sacrum and ilium. Intended uses include hook and sacral screw fixation to the lumbar spine, noncervical spine and to the T1-S1 spine; and hook and sacral/iliac screw fixation to the noncervical spine. The indications are degenerative disc disease defined as back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudoarthrosis, or failed previous fusion (pseudoarthrosis).

When used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, The Spiral Radius 90-D™ SST

System is indicated for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of solid fusion mass.

In addition, when used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, the Spiral Radius 90-D™ SST System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

MATERIALS: The material used is medical grade stainless steel material that conforms to ASTM F138.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 15 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Luis Nesprido
Senior Associate, Regulatory Affairs
United States Surgical
A Division of Tyco Healthcare Group, LP
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K012273
Trade Name: Spiral Radius 90-D™ SST System
Regulatory Number: 888.3050, 888.3060, and 888.3070
Regulatory Class: II
Product Code: MNH, KWP, KWQ, and MNI
Dated: July 18, 2001
Received: July 19, 2001

Dear Ms. Nesprido:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. M. Witten', followed by a small flourish.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

V. Indications for Use

510(k) Number (if known):

K012273

Device Name:

Spiral Radius 90-D™ SST System

Indications For Use:

The components of the Spiral Radius 90-D™ SST System are indicated for spinal fixation.

When used as an anterolateral/anterior system consisting of rods and screws, the levels of attachment are the lumbar, thoracic and cervical spines. The points of attachment and methods are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T6-L5) and the anterior vertebral bodies of the cervical spine. The indications are degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or failed previous fusion (pseudoarthrosis).

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In addition, when used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, the Spiral Radius 90-D™ SST System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓

OR Over-

[Signature]
(Division Sign-Off)

Use:

(Per 21 CFR 801.109)

Division of General, Restorative
and Neurological Devices

510(k) Number

K012273